Economic Impact Analysis
Virginia Department of Planning and Budget

2 VAC 5-585 – Retail Food Establishment Regulations
Department of Agriculture and Consumer Services
January 24, 2006

Summary of the Proposed Regulation

The Board of Agriculture and Consumer Services (board) proposes to amend and repeal the existing regulation 2 VAC 5-580 (Rules and Regulations Pertaining to the Sanitary and Operating Requirements in Retail Food Stores) to provide practical, science-based guidance and manageable, enforceable provisions for mitigating risk factors known to cause foodborne disease. The proposed regulation will adopt appropriate portions of the 2001 edition and 2003 supplement of U.S. Food and Drug Administration (FDA)'s Food Code and will be consistent with regulations enforced by the Virginia Department of Health (VDH) in restaurants and food service operations. Major changes include:

(1) The required cold-holding temperature for most potentially hazardous foods[1] will be reduced from 45° F to 41° F. For retail food establishments whose refrigeration equipment cannot achieve 41° F, a five-year phase-in period is allowed for modification or replacement of the equipment.

(2) The person in charge will be required to demonstrate knowledge of foodborne disease prevention, application of Hazard Analysis Critical Control Point principles (HACCP),[2] and the requirements of the regulation.

[1] According to the proposed regulation, "Potentially hazardous food" means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting: (i) the rapid and progressive growth of infectious or toxigenic microorganisms; (ii) the growth and toxin production of Clostridium botulinum; or (iii) in raw shell eggs, the growth of Salmonella enteritidis. "Potentially hazardous food" includes an animal food (a food of animal origin) that is raw or heat-treated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not acidified or otherwise modified at a food processing plant in a way that results in mixtures that do not support growth as specified above in this definition.

[2] "HACCP Plan" means a written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

(3) A retail food establishment performing certain food processing operations that are typically not performed at the retail level will be required to obtain a variance[3] from Virginia Department of Agriculture and Consumer Services (VDACS) and maintain a validated HACCP plan.

(4) For foods of animal origin that are to be consumed raw, undercooked or not otherwise processed to eliminate pathogenic microorganisms, a disclosure statement will be required indicating that the foods have not been processed to eliminate pathogens and consumption of such foods significantly increases risk of foodborne illness to the consumers.

(5) The proposed regulation will also provide more flexibility for the retail segment of the food industry in how they choose to alleviate food safety problems or foodborne disease risk factors, without compromising food safety and public health. For example, an expansion of the time and a more flexible protocol will be provided for properly cooling hot foods; the required hot-holding temperature will be reduced from 140° F to 135° F; the retail food establishment will be allowed to use time, rather than the typical time and temperature, as a public health control as long as appropriate procedures are followed; and restrictions on animals will be relaxed to allow service animals controlled by disabled persons under certain conditions.

Results of Analysis

There is insufficient data to accurately compare the magnitude of the benefits versus the costs. Detailed analysis of the benefits and costs can be found in the next section.

Estimated Economic Impact

Foodborne illnesses are defined as diseases, usually either infectious or toxic in nature, caused by agents that enter the body through the ingestion of food. Every person is at risk of foodborne illness.[4] Foodborne disease in the United States is a major cause of personal distress, preventable death, and avoidable economic burden. The Centers for Disease Control and Prevention (CDC) estimate that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year. The yearly cost of all

[3] According to the proposed regulation, "Variance" means a written document issued by VDACS that authorizes a modification or waiver of one or more requirements of 2 VAC5-585 if, in the opinion of VDACS, a health hazard or nuisance will not result from the modification or waiver.

foodborne diseases in this country is estimated to be 5 to 6 billion dollars in direct medical expenses and lost productivity. Infections with the bacteria *Salmonella* alone account for $1 billion yearly in direct and indirect medical costs.[5]

The current regulation, 2 VAC 5-580 (Rules and Regulations Pertaining to the Sanitary and Operating Requirements in Retail Food Stores), adopted by the board on February 25, 1986, was based on a model document entitled *Retail Food Store Sanitation Code* which was developed by the Association of Food and Drug Officials and the U.S. FDA and was the forerunner to the FDA Food Code. The FDA Food Code was first published in 1993, but was not widely adopted until controversial issues were successfully refined. Now the FDA Food Code is being accepted as the standard for regulation of retail food establishments.[6] The board proposes to adopt the appropriate portions of the 2001 edition and 2003 supplement of the FDA food code and amend the current regulations so as to provide a retail food store regulation that is based on the most current, sound science available in order to mitigate risk factors[7] known to cause foodborne illness.

Adoption of appropriate portions of the FDA Food Code will also ensure that the retail food store regulations enforced by VDACS be consistent with those being enforced by most of the other states as well as regulations enforced by VDH in similar types of food establishments. The Virginia General Assembly has passed legislation that provides the authority for both VDACS and VDH to concurrently adopt the same version of the FDA Food Code through an expedited adoption process as long as both regulations have the same effective date. Consequently, VDH will be pursuing the process for adoption of the 2001 version of the FDA Food Code during the same time as VDACS. Once both regulations are finalized, they will have the same effective date, and at that point VDACS and VDH will be administering the same food safety standards within all portions of the retail segment of Virginia's food industry. A much

[4] Source: the World Health Organization.
[5] Source: National Institute of Health, U.S. Department of Health and Human Services. http://www.niaid.nih.gov/factsheets/foodbornedis.htm

[6] According to VDACS, as of March 2005, 21 states have adopted the 1999 version and 16 have adopted the 2001 version of FDA Food Code.
[7] According to VDACS, the five major risk factors contributing to foodborne illness are: (i) improper holding temperatures; (ii) inadequate cooking, such as undercooking raw shell eggs; (iii) contaminated equipment; (iv) food from unsafe sources; and (v) poor personal hygiene.

greater level of uniformity in the regulations enforced by the two agencies will reduce confusion and enhance industry conformance with acceptable procedures and practices.

The FDA Food Code has established five key public health interventions for control of the major risk factors[8] and for protection of consumer health, which are embodied in the proposed regulations: (i) demonstration of knowledge; (ii) employee health controls; (iii) controlling hands as a vehicle of contamination; (iv) time and temperature parameters for controlling pathogens; and (v) consumer advisories.

One of the major proposed regulatory changes is that the required cold-holding temperature for most of the potentially hazardous foods will be 41° F or below, unless 45° F is otherwise permitted. Retail store establishments are given a five-year phase-in period to upgrade or replace the equipment. Currently, the required refrigeration temperature for potentially hazardous foods is 45° F or below. This 4° F reduction in temperature will require that the retail segment of the food industry maintain refrigeration equipment that can achieve the lower temperature. Based on data supplied by FDA, manufacturers of refrigeration equipment have been manufacturing for more than 20 years food refrigeration units that will maintain the 41° F temperature. Units manufactured at the upper end of that time line may require some modification, the average cost of which is $200.[9] However, some establishments, mostly in rural or economically challenged areas, use a refrigeration equipment of more than 30 years old which probably can not be modified to achieve the lower temperature. Therefore, a replacement is needed with a cost of $2,500 on average for one 49-cubic-foot refrigeration unit.[10]

According to VDACS, of the 8,725 retail food establishments, 3,509 are major retail food store chains which already meet the lower temperature requirement. Supposing all of the remaining 5,216 retail food stores must either modify or replace their existing refrigeration equipment, with 80% (4,172) modifying and 20% (1,044) replacing, the estimated cost statewide will be up to $200 x 4,172 + $2,500 x 1,044 = $3,444,400. Provided that this increased cost will be spread evenly among the five years, the estimated annual cost will be up to $688,880 statewide.

[8] Ibid.
[9] Source: VDACS.
[10] Source: VDACS.

The proposed regulation will require that the person in charge at the retail food establishment demonstrate knowledge of foodborne disease prevention, application of Hazard Analysis Critical Control Point principles, and the other requirements of the regulation. Options for the demonstrations include complying with this regulation by having no violations during the inspection by VDACS, or being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program,[11] or responding correctly to the inspector's questions as they relate to the specific food operation.

If a retail food establishment chooses to perform certain food processing operations that are typically not performed at the retail level (such as smoking, curing, using additives or acidifying, reduced oxygen packaging, custom processing of animals not covered by the Meat and Poultry Inspection Program, etc.), it will be required to obtain a variance from VDACS and maintain a validated HACCP plan. Requirement of obtaining a variance and maintaining a HACCP plan will ensure that the retail store has the proper procedures for those operations so as to guarantee food safety. According to VDACS, although not required in the current regulation, the retail food stores have to provide certain information to prove that they can process those food operations successfully and safely, which is similar to those included in the variance request. Therefore, requirement of variance request will likely not cause significant cost. However, there might be additional costs associated with preparation of HACCP plans, which will vary from several hours to several days depending on how complicated the plan is and whether current guidance for the plan is available.

For foods of animal origin that are to be consumed raw, undercooked or not otherwise processed to eliminate pathogenic microorganisms, a disclosure statement is required to be used to indicate that the foods have not been processed to eliminate pathogens and consumption of such foods significantly increases risk of foodborne illness to the consumer. This requirement will keep consumers informed of the potential risk and help them make appropriate decisions.

The proposed regulation also provides more flexibility for the retail food establishments in how they choose to alleviate food safety problems or foodborne disease risk factors, without

[11] According to the proposed regulation (5 VAC 5-585-40), "accredited program" means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals.

compromising food safety or public health. Firstly, an expansion of time and a more flexible protocol are proposed for cooling hot foods. Under the current regulation, potentially hazardous food requiring refrigeration after preparation shall be cooled to an internal temperature of 45°F within four hours. The proposed regulation requires that cooked potentially hazardous foods shall be cooled within two hours from 135°F to 70°F, and within a total of six hours from 135°F to 45°F, or 41°F. According to VDACS, it has been scientifically proved that cooked potentially hazardous foods that are cooled from the hot-holding temperature to 70°F within two hours can be safely cooled to the cold-holding temperature within another four hours, therefore this regulatory change allows more flexibility in cooling hot foods without compromising food safety or public health. Secondly, the proposed regulation allows time only, rather than time in conjunction with temperature that are traditionally employed, to be used as a public health control as long as proper procedures are followed. Thirdly, the required hot-holding temperature for potentially hazardous food will be reduced from 140° F to 135° F. According to VDACS, it has been shown scientifically that food safety will be maintained if the required hot-holding temperature is lowered to 135° F. Finally, under certain conditions, service animals will be allowed by the disabled persons. The above regulatory changes slightly reduce costs for the retail store establishments.

In summary, the proposed regulation will provide the necessary guidance to the retail food industry that is based on the most current sound science available for controlling risk factors and implementing intervention strategies, which will enhance the safety of food products sold through the retail segment of the food industry and protect the health and welfare of the citizens. On the other hand, the proposed reduction of the required cold-holding temperature will cause an increase in cost for many retail food establishments, which will commensurately reduce their profits. The yearly increased cost is estimated to be up to $688,880 statewide during the five-year phase-in period. Since there is insufficient data to accurately estimate by how much the frequency of foodborne illnesses will be reduced, the benefits of the proposed regulatory changes can not be quantified. Thus whether the total benefit exceeds the total cost cannot be accurately estimated at this time.

Businesses and Entities Affected

Among the 8,725 Retail food establishments, 5,216 that are not major retail food store chains may have to modify or replace their refrigeration equipment due to the reduction of the required cold-holding temperature from 45° F to 41° F. Therefore, the proposed regulatory change will increase their costs and commensurately reduce their profits. The estimated total annual cost will be up to $688,880 statewide during the five-year phase-in period. On the other hand, the proposed regulation will provide practical, science-based guidance and manageable, enforceable provisions for mitigating risk factors known to cause foodborne disease, therefore, the public (7.1 million) will benefit from reduction or elimination of the foodborne illness risk factors and enhanced food safety.

Localities Particularly Affected

The proposed regulation will not particularly affect any localities in the Commonwealth.

Projected Impact on Employment

Reduction of the required cold-holding temperature from 45° F to 41° F will increase costs for the retail food stores that have to modify or replace their refrigeration equipment. This increase in cost will commensurately reduce their profits and may have a small negative impact on the number of people employed.

Effects on the Use and Value of Private Property

Retail food establishments whose current refrigeration equipment can not achieve 41° F will have to upgrade or replace their equipments and incur a cost of $200 for modification and $2,500 for replacement with one 49-cubic-foot refrigeration unit. The increased cost will commensurately reduce their profits and will likely have a small negative impact on the use and value of their property.

Small Businesses: Costs and Other Effects

VDACS estimates that 90% of the 5,216 (4,694) stores that are not major retail food chain stores are small businesses. They may have to modify or replace their refrigeration equipments if their current refrigeration equipment can not achieve 41° F. Given that the estimated total cost for the 5,216 stores being $3,444,400, the estimated total cost for the small businesses will be 90% x $3,444,400 = $3,099,960. Supposing that this increased cost will be

spread evenly among the five years, the estimated annual cost will be up to $619,992 for the small businesses statewide.

Small Businesses: Alternative Method that Minimizes Adverse Impact

The proposed regulation will provide a practical, science-based guidance for controlling risk factors known to cause foodborne diseases, and will result in cost savings in terms of direct medical expenses and lost productivity associated with foodborne diseases. There will be no alternative method that will achieve the same benefit while having a smaller adverse impact.

Legal Mandate

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.H requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. The analysis presented above represents DPB's best estimate of these economic impacts.